

## § 720.5

## 21 CFR Ch. I (4–1–05 Edition)

(ii) Mouthwashes and breath fresheners (liquids and sprays).

(iii) Other oral hygiene products.

(10) *Personal cleanliness.* (i) Bath soaps and detergents.

(ii) Deodorants (underarm).

(iii) Douches.

(iv) Feminine hygiene deodorants.

(v) Other personal cleanliness products.

(11) *Shaving preparations.* (i) Aftershave lotions.

(ii) Beard softeners.

(iii) Men's talcum.

(iv) Preshave lotions (all types).

(v) Shaving cream (aerosol, brushless, and lather).

(vi) Shaving soap (cakes, sticks, etc.).

(vii) Other shaving preparation products.

(12) *Skin care preparations, (creams, lotions, powder, and sprays).* (i) Cleansing (cold creams, cleansing lotions, liquids, and pads).

(ii) Depilatories.

(iii) Face and neck (excluding shaving preparations).

(iv) Body and hand (excluding shaving preparations).

(v) Foot powders and sprays.

(vi) Moisturizing.

(vii) Night.

(viii) Paste masks (mud packs).

(ix) Skin fresheners.

(x) Other skin care preparations.

(13) *Suntan preparations.* (i) Suntan gels, creams, and liquids.

(ii) Indoor tanning preparations.

(iii) Other suntan preparations.

(d) Ingredients in the product should be listed as follows:

(1) A list of each ingredient of the cosmetic product in descending order of predominance by weight (except that the fragrance and/or flavor may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data).

(2) An ingredient should be listed by the name adopted by the Food and Drug Administration (FDA) for the ingredient pursuant to § 701.3(c) of this chapter.

(3) In the absence of a name adopted by FDA pursuant to § 701.3(c) of this chapter, its common or usual name, if

it has one, or its chemical or technical name should be listed.

(4) If an ingredient is a mixture, each ingredient of the mixture should be listed in accordance with paragraphs (d)(2) and (d)(3) of this section, unless such mixture is a formulation voluntarily registered on Form FDA 2512, in which case such mixture should be identified as "fragrance," "flavor," "fragrance and flavor" or "base formulation," as appropriate, and by stating its FDA-assigned cosmetic product ingredient statement number.

(5) When the manufacturer or supplier of a fragrance and/or flavor refuses to disclose ingredient data, the fragrance and/or flavor should be listed as such. The nonconfidential listing of the product name and/or trade name or name of the manufacturer or supplier of each proprietary fragrance and/or flavor mixture is optional.

(e) A separate Form FDA-2512 should be filed for each different formulation of a cosmetic product. However, except for the hair coloring preparations listed in paragraph (c)(6) of this section for which a statement for each shade of such product is required, a single Form FDA-2512 may be filed for two or more shades of a cosmetic product where only the amounts of the color additive ingredient used are varied or in the case of flavors and fragrances where only the amounts of the flavors and fragrances used are varied.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0030)

[39 FR 10060, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981; 57 FR 3129, Jan. 28, 1992]

## § 720.5 [Reserved]

## § 720.6 Amendments to statement.

Changes in the information requested under §§ 720.4 (a)(3) and (a)(5) on the ingredients or brand name of a cosmetic product should be submitted by filing an amended Form FDA 2512 within 60 days after the product is entered into commercial distribution. Other changes do not justify immediate amendment, but should be shown by filing an amended Form FDA 2512 within a year after such changes. Notice of